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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,302	MUELLER-WALZ, RUDI	
	Examiner	Art Unit	
	Nicoletta Kennedy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/31/06 and 8/25/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-33 are currently pending.

Priority

This application, filed March 31, 2006, is a national stage entry of PCT/IB04/03481 filed October 8, 2004, and claims foreign priority to United Kingdom application 0323684.1, filed on October 9, 2003. Applicants have provided a certified copy of the United Kingdom application.

Information Disclosure Statement

1. The information disclosure statement filed August 25, 2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 10/574,334. Both claims are directed to a pharmaceutical aerosol formulation for use in a metered dose inhaler (MDI) comprising formoteral fumarate di-hydrate in suspension, a propellant and ethanol, wherein the formoterol fumarate di-hydrate has a water content of about 4.8 to 4.28% by weight. Each claim claims the same scope This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

4. Claims 10-12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 10-12 of copending Application No. 10/574,334. Claim 10 in each application is drawn to a formulation according to claim 1 where the formoterol fumarate di-hydrate is present in an amount of 0.001 to 0.1% by weight of the formulation. Claim 11 in each application is drawn to the formulation containing a cromone selected from the group consisting of a pharmaceutically acceptable salt of cromoglycinic acid, nedocromil, or mixtures thereof. Claim 12 of each application is directed to a formulation wherein the cromone is present in an amount from 0.001 to 1%. The instant application and copending application claim the same scope. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

5. Claim 16 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 16 of copending Application No. 10/574,334. Both claims are directed to a formulation wherein the propellant is employed in an amount of greater

than 90% by weight and claim the same scope. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

6. Claims 18-24 and 26-28 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 18-24 and 26-28 of copending Application No. 10/574,334. Claims 18 and 19 in each application claim a surfactant chosen from the same Markush group and claim that the surfactant is present from 0.001 to 1% by weight. Claim 20 in each application claims a moisture content in the range of 50ppm to 800 ppm. Claim 21 in each application claims a vial. Claim 22 in each application claims an uncoated aluminum vial. Claim 23 in each application claims a dosage of formoterol fumarate di-hydrate of about 3 to 15 micrograms. Claim 24 in each application claims a dosage of steroid of about 10 to 1000 micro-grams per puff. Claim 26 in each application claims a mean delivered dose of the active substances of no more than +/- 15% of the dosage stated on the label. Claim 27 of each application claims a metered dose inhaler containing the vial of claim 21 in each application. Claim 28 of each application claims a method of producing a pharmaceutical aerosol formulation comprising drying the formoterol fumarate di-hydrate to a water content of 4.8 to 4.28%. Each claim claims the same scope as the corresponding claim of the copending application. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

7. Claim 33 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 33 of copending Application No. 10/574,334. Both claims are directed to a metered dose inhaler containing the vial according to claim 22, rejected

under provisional double patenting above and claim the same scope. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-2, 7, 10, 13-16, 21, 23-24, 27-28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (US 2002/0103260) in view of Trofast et al. (WO 92/18110) and Trofast (WO 01/89491).

Regarding claims 1 and 28, Clarke et al. teach an aerosol composition for a metered dose inhaler comprising formoterol fumarate dihydrate, ethanol, and HFA 134a (para. 0024). However, Clarke et al. fail to teach the water content of formoterol fumarate di-hydrate. Trofast et al. cure this deficiency.

Trofast et al. teach a process for providing water-soluble micronized substances wherein the residual water from the micronized substance is reduced by drying at an elevated temperature and/or in a vacuum (abstract). Trofast et al. explain that the invention relates to a process for providing water-soluble micronized substances which can be stored and used while maintaining the aerodynamic properties required for inhalation of such substances (p. 3, lines 5-14). The process may specifically be used on anti-asthmatic substances (claim 9).

Trofast teaches that formoterol fumarate dihydrate, when combined with a reactive species such as an aldehyde, is prone to degradation (p. 2 line 25 –p. 3, line 2). Trofast explains that when formoterol fumarate dihydrate is combined with lactose monohydrate, they form degradation products (p. 3, lines 11-16). Additionally, relative humidity influences the stability of the powder (p. 3, lines 19-20).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Clarke et al. with those of Trofast et al. and Trofast to modify the water content of a formoterol fumarate dihydrate. One of ordinary skill would have been motivated to do modify the water content of a formoterol fumarate dihydrate formulation to increase stability since the used of lactose monohydrate is known to form degradation products when combined with formoterol fumarate dihydrate (Trofast, p. 3, lines 11-16). The primary reference, Clarke et al., teaches combining formoterol fumarate dihydrate with lactose monohydrate for use as an anti-asthmatic medication.Trofast teaches that formoterol fumarate dihydrate is unstable when combined with a reactive species such as lactose monohydrate. Trofast

et al. teach a remedy for this instability by teaching a method of drying anti-asthmatic substances to stabilize them for longer shelf life.

Although neither Clarke et al., Trofast et al., or Trofast teach the specific water content of formoterol fumarate di-hydrate, MPEP 2144.05 states that " where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" quoting *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The combination of Clarke et al., Trofast et al. and Trofast et al. B teach that the stability of formoterol fumarate may be improved by drying the powder prior to mixing it with the other ingredients of an anti-asthmatic aerosol composition. Thus, although the water content is not disclosed, it is not inventive to discover a workable range for the water content discernable by routine experimentation.

Regarding claims 2 and 7, Clarke et al. teach that the aerosol composition for a metered dose inhaler is comprised of formoterol fumarate dihydrate, fluticasone propionate, a steroid (para. 0024). The steroid may be in suspension in the propellant (claim 8).

Regarding claim 10, Clarke et al. teach that the formoterol fumarate dihydrate is present at 0.012% by weight of the composition (para. 0024).

Regarding claims 13-15, and 32, Clarke et al. teach that the aerosol composition comprises HFA 134a and HFA 227, both hydrofluoroalkanes (para. 0024).

Regarding claim 16, Clarke et al. teach that the propellants (HFA 134a and HFA 227) are present at 97.238% by weight of the composition (para. 0024).

Regarding claim 17, Clarke et al. teach that ethanol is present at 2.5000% by weight of the composition (para. 0024).

Regarding claim 21, Clarke et al. teach that the inhalation device may be an aerosol vial (para. 0015).

Regarding claim 23, Clarke et al. teach that the metered dose inhaler may deliver 6 to 24 micrograms of formoterol fumarate dihydrate (para. 0017). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range overlaps the range taught by Clarke et al. and is therefore prima facie obvious.

Regarding claim 24, Clarke et al. teach that the metered dose inhaler may deliver from 25 to 500 micrograms of fluticasone propionate dihydrate (para. 0017). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range overlaps the range taught by Clarke et al. and is therefore prima facie obvious.

Regarding claim 27, Clarke et al. teach that the aerosol vial may be a metered dose inhaler (para. 0015).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Clarke et al. with those of Trofast et al. and Trofast. One of ordinary skill would have been motivated to do so because Trofast teaches that formoterol fumarate dihydrate is unstable when combined

with a reactive species such as lactose monohydrate, Trofast et al. teach a method of drying anti-asthmatic substances to stabilize them for longer shelf life, and Clarke et al. teach combining formoterol fumarate dihydrate with lactose monohydrate for use as an anti-asthmatic medication.

11. Claims 3-6, 21-22, 26 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (US 2002/0103260) in view of Trofast et al. (WO 92/18110) and Trofast (WO 01/89491) as applied to claims 1-2, 7, 10, 13-16, 21, 23-24, 27-28 and 32 above, and further in view of Kordikowski et al. (US 2003/0223939).

The combination of Clarke et al., Trofast et al. and Trofast teaches each limitation of claim 1, from which claim 2 depends, and each limitation of claim 2, from which claims 3-6 depend. However, these references fail to teach the fine particle fraction of the delivered dose of formoterol fumarate dihydrate or steroid. Kordikowski et al. cure this deficiency.

Regarding claims 3 and 5, Kordikowski et al. teach particulate suspensions comprising active substances in particulate form suspended in hydrofluoroalkane propellants for use in metered dose inhalers (abstract). These suspensions are stored at 75% relative humidity and at 40°C (para. 0095) for varying periods of time, include 6 months (para. 0080). The fluid suspensions allow the aerosol formulations used in metered dose inhalers to give a more uniform dosing rate throughout the useable life of the inhaler (para. 0081). The relative standard deviation in the quantity of active substance delivered in each dose is no more than 15% (para. 0084). MPEP 2144.05 states that “[i]n the case where the claimed ranges ‘overlap or lie inside ranges

disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). This "no more than 15%" parameter disclosed by Kordikowski et al. fits within the variance of +/- 25% and the claimed range is therefore prima facie obvious.

Regarding claims 4 and 6, Kordikowski et al. teach particulate suspensions comprising active substances in particulate form suspended in hydrofluoroalkane propellants for use in metered dose inhalers (abstract). Kordikowski et al. specifically teach that fluticasone propionate in HFA 134a (Figure 5) and formoterol fumarate dihydrate (para. 0096) have a fine particle fraction of 35% (paras. 0020 and 0132). This fine particle fraction is delivered through a metered dose inhaler (para. 0021).

Regarding claims 21-22 and 33, Kordikowski et al. teach that the aluminum metered dose inhaler need not be coated (paras. 0139-0141).

Regarding claim 26, Kordikowski et al. teach that the relative standard deviation in the quantity of active substance delivered in each dose is preferably no more than 15% (para. 0084). Although Kordikowski et al. does not specifically state that this active substance doseage is stated on the label, it is well known in the art that inhaler labels specify the quantity of active substance delivered in each dose.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Clarke et al., Trofast et al. and Trofast with those of Kordikowski et al. with regard to claims 4 and 6, to formulate a composition with a fine particle fraction of at least 35%. One of ordinary skill would have been motivated to do so because a fine particle fraction of at least 35% will result in

more efficient delivery of the active substance to the deep lung (Kordikowski et al., para. 0133). With regard to claims 3, 5 and 26, one of ordinary skill in the art would have been motivated to have a variance of no more than +/-25% of the mean delivered dose because this improves the accuracy of the dosage amount. Additionally, with regard to claims 21-22 and 33, Kordikowski et al. teach a method of improving flocculation behavior such that less ethanol than usual is required as a co-solvent and such that the aluminum metered dose inhaler need not be coated, simplifying the manufacturing process for an aerosol metered dose inhaler composition.

Claims 8-9, 11-12, 18-19, 25 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (US 2002/0103260) in view of Trofast et al. (WO 92/18110) and Trofast (WO 01/89491) as applied to claims 1-2, 7, 10, 13-16, 21, 23-24, 27-28 and 32 above, and further in view of Keller et al. (US 6,475,467).

The combination of Clarke et al., Trofast et al. and Trofast teaches each limitation of claims 1 or 2, from which claims 8-9, 11-12 and 18-19 depend, each limitation of claim 13, from which claims 29 and 31 depend, and each limitation of claim 21, from which claim 25 depends. However, these references fail to teach that salts of cromoglycic acid and or nedocromil may be used in the formoterol fumarate dihydrate composition. Additionally, these references fail to teach that fluorochlorocarbons such as F218 may be used as the propellant. Finally, these references fail to teach that ciclesonide may be used in combination with formoterol fumarate dihydrate. Instead, they teach the efficacious amounts and weight % by weight of the composition for the steroid fluticasone propionate. Keller et al. cure these deficiencies.

Regarding claim 8, Keller et al. teach that a combination of formoterol and ciclesonide may be suspended in an aerosol composition (column 5, lines 40-47).

Regarding claim 9, Keller et al. teach that the active compounds may comprise from 0.0001 to 0.2% by weight of the composition (column 6, lines 1-4). In examples where a combination of active compounds are used, the steroid is present in a larger amount than the formoterol. Therefore, the steroid would be from at least 0.00005% to 0.1% by weight of the composition. MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the range in the instant claim overlaps the range disclosed by Keller et al. and is therefore prima facie obvious.

Regarding claim 11, Keller et al. teach the use of pharmaceutically acceptable salts of cromoglycic acid or nedocromil as carriers in an aerosol suspension formulation (abstract). The active compound in the formulation may be formoterol (column 5, line23).

Regarding claim 12, Keller et al. teach that the cromoglycic acid salts or nedocromil salts are present at not over approximately 0.7%, preferably present at 0.007 to 0.36%, and particularly present at 0.015 to 0.15% by weight of the total formulation (column 6, lines 50-56). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90

(CCPA 1976). In the instant case, the claimed range overlaps the ranges disclosed by the prior art and is therefore prima facie obvious.

Regarding claim 18, Keller et al. teach that the aerosol formulations may contain surface-active agents such as oleic acid, lecithin, sorbitan trioleate, cetylpyridinium chloride, benzalkonium chloride, polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (20) sorbitan monooleate, polyoxypropylene/polyoxyethylene block copolymers, polyoxypropylene/polyoxyethylene/ethylenediamine block copolymers, ethoxylated castor oil and the like (column 9, lines 17-25).

Regarding claim 19, Keller et al. teach that the proportion of surface-active agents, if present, can preferably be approximately 0.0001 to 1% by weight of the formulation (column 9, lines 25-27).

Regarding claim 25, Keller et al. teach that ciclesonide may be used as the pharmaceutically active compound administered as suspension aerosols (column 5, lines 13-15 and line 25). The ciclesonide may be administered in an efficacious dose of approximately 0.1 to 100 micrograms per puff of spray (column 5, lines 56-59). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range overlaps the ranges disclosed by the prior art and is therefore prima facie obvious.

Regarding claims 29-31, Keller et al. teach that suitable non-toxic liquid propellants for aerosol formulations include trichloro-monofluoromethane (F11), dichlorodifluoromethane (F12), monochlorotrifluoromethane (F13), dichloro-monofluoromethane (F21), monochlorodifluoromethane (F22), monochloromonofluoromethane (F31), 1,1,2-trichloro-1,2,2-trifluoroethane (F113), 1,2-dichloro-1,1,2,2-tetrafluoroethane (F114), 1-chloro-1,1,2,2,2-pentafluoroethane (F115), 2,2-dichloro-1,1,1-trifluoroethane (F123), 1,2-dichloro-1,1,2-trifluoroethane (F123a), 2-chloro-1,1,1,2-tetrafluoroethane (F124), 2-chloro-1,1,2,2-tetrafluoroethane (F124a), 1,2-dichloro-1,1-difluoroethane (F132b), 1-chloro-1,2,2-trifluoroethane (F133), 2-chloro-1,1,1-trifluoroethane (F133a), 1,1-dichloro-1-fluoroethane (F141b) and 1-chloro-1,1-difluoroethane (F142b), alkanes such as *propane* (with regard to instant claim 30), butane and isobutane, fluorinated alkanes such as *octafluoropropane (F218)* (with regard to instant claim 31)(column 7, lines 7-25).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Clarke et al., Trofast et al. and Trofast with those of Keller et al. One of ordinary skill would have been motivated to combine the teachings of Keller et al. with those of Clarke et al., Trofast et al. and Trofast with regard to claims 8-9 and 25 because Keller et al. teach the simple substitution of a known steroid. One of ordinary skill would have been motivated to do so with regard to claims 11-12 because Keller et al. teach that disodium cromoglycate and nedocromil sodium are used in known metered-dose aerosols in a therapeutically or phophylatically efficacious amount. One of ordinary skill would have been motivated

to combine the teachings of Keller et al. with those of Clarke et al., Trofast et al. and Trofast with regard to claims 18-19 because Keller et al. teach that the aerosol formulations may comprise a surfactant to lower the surface tension of the formulation. One of ordinary skill would have been motivated to combine the teachings of Keller et al. with those of Clarke et al., Trofast et al. and Trofast with regard to claims 29-31 because Keller et al. teach the simple substitution of known propellants.

12. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (US 2005/0152846) read in view of Clarke et al. (US 2002/0103260).

Davies et al. teach an inhalable pharmaceutical formulation comprising formoterol or one of its pharmaceutically acceptable salts such as fumarate (abstract, para. 30). Davies et al. additionally teach that the formulation comprises a liquefied HFA propellant and ethanol as a co-solvent (paras. 0057 and 0059). Additionally Davies et al. teach that the stability of the formulation is improved by having lower than 500 ppm of water based on the total weight of the formulation (paras. 0073 and 0112). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range overlaps the range disclosed by Davies et al. and is thus prima facie obvious.

However, Davies et al. do not teach that the formoterol fumarate is formoterol fumarate dihydrate. Clarke et al. cure this deficiency.

Clarke et al. teach an aerosol composition for a metered dose inhaler comprising formoterol fumarate dihydrate, ethanol, and HFA 134a (para. 0024).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Davies et al. with those of Clarke et al. to use the di-hydrate form of formoterol fumarate. One of ordinary skill would have been motivated to do so because the di-hydrate form of formoterol fumarate is more quickly and readily absorbed into the lungs.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicoletta Kennedy/
Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611